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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,543	07/27/2001	Konrad Basler	Q-60361	9256

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EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	13

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/915,543	BASLER ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17,19-21,23-34,44,61-63,69 and 70* is/are pending in the application.

4a) Of the above claim(s) *17,19,25-34,61,62,69 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16,20,21,23,24,44 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 13-16, 20, 21, 23, 24, 44 and 63 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the inventions of Groups III and V-IX should be examined together because these inventions are related to one or more aspects of the invention of Group II. Applicant argues that the antibodies of Group V can only be made using the protein of Group II. Applicant argues that method of isolation of binding proteins of Group III can only be performed using the polypeptides of Group II or the antibodies of Group V. Applicant argues that the identification of compounds interfering with binding partners of legless protein can only be carries out with the protein of Group II and points to examples in the specification demonstrating the screening process. Applicant argues that the common basis of Groups VII, VIII and IX are small bioorganic molecules, synthetic polymers or small polypeptides that stimulate or antagonize the function of the protein of Group II and methods of screening for these molecules, which require knowledge of the protein of Group II. This is not found persuasive because each of the inventions of Groups II and V-IX is a separate and distinct invention from the elected invention of Group II, as detailed in the restriction requirement set forth in the Office action mailed 09-19-2002. Applicant argues that there are aspects of each of these inventions that are related, however, Applicant has not demonstrated that each of the claimed inventions is not distinct from the invention of Group II. As detailed in the restriction requirement set forth in the prior Office action, the antibodies of Group V have a different function than the

proteins of Group II, and further, have a different classification and different search and, therefore, are properly restricted. Although the polypeptides of Group II may be used in the methods of Group III, the polypeptides of Group II can be used in a materially different method than the method of Group III, and the methods of Group III have a different classification and search than the polypeptides of Group II and, therefore, are properly restricted from Group II. Each of the inventions of Group VII and VIII are directed to compounds that have functions distinct from those of the polypeptides of Group II, are classified differently and require a different search from Group II and are properly restricted. The screening methods of Group IX may use the polypeptides of Group II, however, the polypeptides of Group II can be used in a materially different method than those of Group IX and have a different classification and require a different search and are properly restricted. Although Applicant argues a relationship between these inventions, the relationship is not such that the inventions are the same invention and are distinct inventions, further, each of these inventions would require a separate search and are classified separately and, therefore, are properly restricted.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17, 19, 25-34, 61, 62, 69 and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Applicant's election with traverse of SEQ ID NO:15 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the sequences of dLgs and hLgs/Bc19 cannot be separated and prosecuted in different applications because the identification of dLgs was a prerequisite for the identification and functional characterization of hLgs/Bc19. This is not found persuasive because each of the separate sequences claimed is distinct in structure (i.e. sequence) and would require a separate search. Applicant's election and the language of the claims in the elected Group do not specify specific sequences and this aspect of the restriction is moot, however, in the event that specific sequences are claimed during the prosecution of this case this restriction requirement will be maintained and Applicant will be required to elect a single sequence of the invention.

Specification

The abstract of the disclosure is objected to because the Abstract is longer than 150. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, 20, 21 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "positive function" in line 4 of the claim. It is unclear what functions would be encompassed in the term "positive functions" as this term is not a term of art, nor has it been defined in the specification. Therefore, the skilled artisan would not know what polypeptides would be encompassed in the claims.

Claim 13 is further indefinite because it recites a protein comprising "derivatives" and "analogs" of a legless gene product. It is unclear what compounds would be encompassed in the terms "derivatives" and "analogs", for example, what types of changes and what degree of changes can occur in a legless gene product and still be considered a "derivative" or "analog", rather than an entirely different molecule.

Claim 13 is further indefinite because it recites a protein comprising "a legless (lgs) gene product, derivatives, fragments and analogs thereof", wherein the alternative forms of the protein are not recited in the alternative. It is unclear whether the claimed protein must comprise each of these forms of the protein (the gene product, derivatives of the gene product, fragments of the gene product and analogs), as recited, which is contrary to the specification, or if these protein forms are meant in the alternative.

Claims 20, 21, 14 and 63 are indefinite for the same reasons due to dependence on claim 13.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16, 20, 21, 23, 24, 44 and 63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO: 15 and 17, which correspond to the human BCL9 and lgs-1 proteins and SEQ ID NO:10, which corresponds to the drosophila lgs protein. SEQ ID NO: 10, 15 and 17 meet the written description provisions of 35 USC 112, first paragraph. However, claims 13-16, 20, 21, 44 and 63 are directed to encompass polypeptides from other species, mutated versions of the polypeptide, polypeptides encoded by allelic variants and splice variants, derivatives and variants of these polypeptides, and so forth. None of these amino acid sequences (or the polynucleotides encoding such) meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 10, 15, and 17, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins (or polynucleotides encoding such), regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen

Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 10, 15 and 17, but not the full breadth of the claim, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-16, 20, 21, 23, 24, 44 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/57188).

Tang et al. disclose, and claim, an isolated polypeptide (SEQ ID NO: 2178 of Tang et al.) that is 99.4% identical to amino acid residues 1-1392 of the instantly disclosed human lgs/BCL9 protein (97% identical to the full length) (SEQ ID NO: 15 of the instant application) (see attached sequence alignment). Tang et al. disclose their polypeptide as a chimeric protein, fused to a heterologous amino acid sequence (see for example pages 27-34), including, for example, a GST moiety, a thioredoxin moiety, an antibody moiety and an epitope tag sequence (see for example page 31). Tang et al. disclose their polypeptide in a pharmaceutical composition, including wherein the protein is in a carrier facilitating the transport of the protein across a cell membrane (see for example, section 4.12.2 Compositions/Formulations). Tang et al. do not disclose their protein as having a "positive function" in the Wnt/Wg-pathway, however, they

disclose their protein as a human BCL9 homologue and their protein meets all of the physical limitations of the claims and their protein is 97% identical (99.4% identical to residues 1-1392) to one embodiment of the claimed invention disclosed in the instant specification and, therefore, would be expected to have a "positive function" in the Wnt/Wg-pathway, absent evidence to the contrary.

Therefore, Tang et al. (WO 01/57188) anticipates claims 13-16, 20, 21, 44 and 63.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere

KAREN LACOURCIERE
PATENT EXAMINER

Karen A. Lacourciere
March 6, 2003